IOWA DEPARTMENT OF INSPECTIONS & APPEALS

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CMS Issues Revised Guidance for Unnecessary Medications

DES MOINES, IOWA (October 3, 2006) - The Iowa Department of Inspections and Appeals (DIA) was recently notified by the Centers for Medicare & Medicaid Services (CMS) that the federal agency is issuing revised guidance for surveying Unnecessary Drugs, Pharmacy Services, Drug Regimen Review, and Labeling and Storage of Drugs and Biologicals. In a Survey and Certification Letter dated September 20, 2006, CMS notes that the current regulatory language dealing with Pharmacy Services is being collapsed into three tags – F425, F428, and F431. The revised surveyor guidelines will become effective December 18, 2006.

The revised interpretative guidelines for Unnecessary Medications contain clarifications of several aspects of medication management and a new medication table that includes medications that are problematic to a nursing home population. CMS' revised guidelines also provide investigative protocols covering both medication and medication regimen issues, and severity guidance for F329.

In its new Pharmacy Services guidance, CMS has combined regulatory guidance presently at Tags F425 through F431 into three remaining Tags – F425, Pharmacy Services; F428, Drug Regimen Review; and F431, Labeling and Storage of Drugs and Biologicals. The new guidance speaks to the provision of pharmacy services for the entire distribution system, from ordering and acquisition to administration and disposal of medications to assure a safe system for each resident. Severity guidance, too, is provided for each of the F Tags.

Unnecessary Medications and Medication Regimen Review

The intent of the new federal guidelines addressing unnecessary medications and medication regimen is to:

- Promote/maintain highest practicable well-being;
- Limit medications, dose and duration to clinically indicated;
- Consider non-pharmacological interventions;
- Minimize adverse consequences, and
- Recognize condition change/decline, evaluate role of medications and modify regimen if needed.

Resident choice and advance directives also are key factors in the interpretive guidelines dealing with medication management. The guidelines stress that a resident has the right to make informed choices about his or her care, and that physicians and staff are to facilitate the resident's decisions while taking into consideration the safety of the resident.

As part of the investigative protocols associated with unnecessary medications, health facilities surveyors are to determine whether the resident receives only those medications clinically indicated in the dose and duration to meet the resident's needs. Additional objectives outlined in the new guidelines include whether the facility and prescriber are monitoring medications for effectiveness and the emergence of adverse consequences.

Pharmacy Services

The intent of the new federal guidelines for pharmacy services focuses on whether the facility is meeting the needs of the resident. Additional guidelines include the following:

- Whether pharmaceutical services are coordinated within the facility,
- Whether pharmaceutical concerns and issues affecting residents and care are being identified and evaluated, and
- Whether only authorized persons are administering medications.

A facility will be found in compliance with the pharmacy services requirements if it provides medications and biologicals for each resident as ordered by the prescriber, develops and implements procedures for the pharmaceutical services, consults with a pharmacist regarding all aspects of pharmaceutical services, and has appropriately licensed or regulated staff to administer medications.

Iowa long-term care facilities participating in the Medicare or Medicaid programs will be subject to the new federal guidelines with all surveys or complaint investigations beginning on or after December 18, 2006. Nursing home staff with questions about the new CMS guidelines should contact their DIA Health Facilities Division program coordinator for clarification.

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